

Docket No.: **UMBC-0012**

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Confirmation No.: 2038

Leah TOLOSA et al.

Group Art Unit: 1657

Serial No.: 10/552,164

Examiner: Bin SHEN

Filed: October 11, 2005

Customer No.: 68733

For: **PROTEINS, SENSORS, AND METHODS OF CHARACTERIZING ANALYTES USING THE SAME**

PRE-APPEAL BRIEF REQUEST FOR REVIEW

U.S. Patent and Trademark Office
Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In response to the Office Action of October 9, 2009, Applicants request that an appeal conference review matters of clear error and omission that Applicants have identified on appeal. Applicants' Notice of Appeal is filed concurrently herewith. Applicants' arguments in support of this Request appear below.

The Rejections under 35 U.S.C. § 112, Second Paragraph Constitute Clear Legal Error.

Claims 1, 2, 4-6, 9, 10 and 12-21 are rejected under 35 U.S.C. § 112, second paragraph. (10/09/09 Office Action at 2.) The Examiner argues that the term “sufficiently small percentage change” in claims 1, 9 and 13 is a relative term which renders the claims indefinite. However, Applicants respectfully submit that the Examiner is reading this term out of context. The full phrase reads “a second detectable quality, comprising a long-lived metal complex label, that undergoes a sufficiently small percentage change when the protein sensing molecule is

bound to the analyte to function as a reference.”

Applicants respectfully submit that this phrase is clear and definite on its face, and that one of ordinary skill in the art would be reasonably apprised of the scope of the invention. The Examiner implies that an actual percentage change needs to be recited in order to make the claim definite. However, doing so would unnecessarily narrow the claim. The claim language itself provides a standard for ascertaining what falls within the scope of the claim. Specifically, the second detectable quality must exhibit a sufficiently small percentage, when the protein sensing molecule is bound to the analyte, so that it can function as a reference. Thus, if the percentage change is such that the second detectable quantity can function as a reference, it falls within the scope of the claim. If the percentage change is such that the second detectable quantity cannot function as a reference then it does not fall within the scope of the claim.

The Rejections under 35 U.S.C. § 112, First Paragraph Constitute Clear Legal Error

Claims 1, 2, 4-6, 10, 12 and 14-21 are rejected under 35 U.S.C. § 112, first paragraph. (10/09/09 Office Action at 3.) The Examiner argues that while the specification is enabling for the long-lived metal complex labels specified in the specification, it does not reasonably provide enablement for all long-lived metal complex labels, especially since there is no definition of a “long-lived metal complex label.”

First, Applicants point out that in the May 20, 2009 Office Action, the Examiner indicates claims 8, 9, 12 and 13 “would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.” (5/20/09 Office Action at 3.) Claim 8 recited “The protein of claim 1, wherein the second detectable quantity comprises a long-lived metal complex label.” In that Office Action, the Examiner made no mention of an enablement issue with respect to claim 8. In reliance on the Examiner’s indication of allowable subject matter, Applicants amended claim 1 to include the features of claim 8, and rewrote

claims 9 and 13 in independent form. In response, the Examiner has decided to issue a 35 U.S.C. § 112, first paragraph rejection against claims that he previously indicated would be allowable if rewritten as he instructed in the 5/20/09 Office Action.

Further, the rejection itself constitutes clear error. To the extent the Examiner has focused on the choice of a particular type of long-lived metal complex label, Applicants respectfully submit that the particular type of long-lived metal complex label to use is simply one of a number of choices the skilled artisan can make when using the presently claimed invention. It is a protein sensing molecule that is being claimed in the subject application, not a particular type of long-lived metal complex label.

The Panel's attention is respectfully drawn to the opinion of the appellate Court in the seminal case of *In re Angstadt*, 537 F. 2d 498 (C.C.P.A. 1976). In *Angstadt*, the claims on appeal were directed to a method of making hydroperoxides using catalysts of a general formula MX_n. Because the specification included examples in which a particular catalyst of general formula MX_n did not yield the desired hydroperoxides, the examiner in that case rejected the claims under 35 U.S.C. § 112, first paragraph, as lacking enablement.

The Court of Customs and Patent Appeals (predecessor to the Court of Appeals for the Federal Circuit), however, reversed the examiner's rejection. Of particular significance here, the Court noted that claims were directed to methods of making hydroperoxides and so, to the extent that a particular catalyst within the generic formula of the claims did not yield the desired product, that particular catalyst was not within the scope of the claims.

The same logic is equally applicable to the pending claims. The Examiner states that it would be an undue burden for one of ordinary skill in the art to test if all the long-lived metal complex labels can be used in the sensing molecule. The specification is replete with examples of long-lived metal complex labels that undergo a sufficiently small percentage change when the protein sensing molecule is bound to the analyte to function as a reference. If a particular long-

lived metal complex label does not undergo a sufficiently small percentage change to function as a reference, then the use of that particular long-lived metal complex label should not be considered to be within the scope of the claim. As quite succinctly noted by the Court in *Angstadt*:

What the dissent seems to be obsessed with is the thought of catalysts which won't work to produce the intended result. Appellants have enabled those in the art to see that this is a real possibility, which is commendable frankness in a disclosure. Without undue experimentation or effort or expense the combinations which do not work will readily be discovered and, of course, nobody will use them and the claims do not cover them. The dissent wants appellants to make everything predictable in advance, which is impracticable and unreasonable.

See In re Angstadt, 537 F.2d 498, 504 (C.C.P.A. 1976)(emphasis added).

The Court's comments above underscore the flaw in the Examiner's arguments in the outstanding Office Action. If certain long-lived metal complex labels will not undergo a sufficiently small percentage change to function as a reference, then the use of those labels should not be considered within the scope of the claim. And perhaps more importantly, if certain long-lived metal complex labels will not successfully function as a reference, then no one will ever bother using them in the inventive molecule and all of this becomes, at best, a purely academic discussion.

The Finality of the 10/09/09 Office Action is Improper

The Examiner made the 10/09/09 Office Action "Final" because the Examiner alleges that Applicants' amendment necessitated the new ground(s) of rejection presented in the Office Action (10/09/09 Office Action at 4.) "Under present practice, second or any subsequent

actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).” (MPEP 706.07(a)) (emphasis added). The Examiner had an opportunity to present the 35 U.S.C. § 112, first paragraph rejection in the 5/20/09 Office Action but did not do so. To the contrary, the Examiner indicated that claims 8, 9, 12 and 13 “would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.” (5/20/09 Office Action at 3.), which the Applicants complied with.

CONCLUSION

The rejections for indefiniteness and enablement constitute clear legal error. Further, the finality of the 10/09/09 Office Action was improper. Therefore, it is respectfully submitted that this application is in condition for allowance. Favorable consideration and prompt allowance are earnestly solicited.

Respectfully submitted,
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